K061126

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: Mar. 15, 2006 MAY - 9 2006

1. Company and Correspondent making the submission:

Name – CyberMed, Inc.
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Contact – Mr. Song Nak Choi/ Manager

2. Device :

Trade/proprietary name	: Accurex
Common Name	: 3D dental image processing software
Classification Name	: Picture archiving and communications system

3. Predicate Devices :

Manufacturer:	CyberMed, Inc.
Device:	V-works™
510(k) Number:	K013878 (Decision Date – 12/07/2001)
Manufacturer:	CyberMed, Inc.
Device:	Vimplant
510(k) Number:	K053155 (Decision Date – 11/23/2005)

4. Classifications Names & Citations :

21CFR 892.2050, LLZ, Picture archiving and communications system, Class2

5. Description :

1) General Description

Accurex™ is a dental imaging software which loads DICOM images taken from CT, MR and provides 3D visualization, 2D image reformation and various diagnosis tools for dentists on PC, laptop or PACS Workstation.

Dentists can do further precise and accurate pre/post-operative diagnosis by using advanced image reformation and generation functionality of Accurex™ such as Panoramic image and Cephalometric x-ray image as well as 3D volume rendering image.

2) Main Function

(1) DICOM 3.0 data Compliance and Management

Users can import DICOM 3.0 data taken from scanning devices such as CT, MRI to the Accurex™'s database. The Accurex™ supports to load different types of DICOM images such as 8/12/16 bits gray images and color images. The imported DICOM images can be stored in Master database, Local databases or Remote PACS servers on intuitive user interface such as Windows Explorer. The Accurex™ supports to make multiple Local databases so it is very convenient for multiple users on one system. Also the Accurex™ supports CD-R/RW to keep necessary DICOM images in CD directly.

(2) Image Display

The Accurex™ supports to load different types of DICOM images such as 8/12/16 bits gray images and color images. And Accurex™ provides 'CINE Player' to display multi-frame DICOM images and also supports a preview image on Window print and DICOM print screen.

(3) Basic Operation

The Accurex™ provides some tools for basic image operation. As 2D image operation tools, it provides Window Level adjusting, Panning, Zooming, Rotation, Flip, Inverting and High-quality Plane zoom. And As 3D image operation tools, it provides Rotation, Panning, Zooming and High-quality 3D zoom.

(4) 2D image reformation

The Accurex™ has the capability of reformatting Panoramic images and Cross-

sectional images as well as basic MPR(Multi-Planar Reformation), thickness MPR, Oblique MPR. Also Accurex™ can generate some radiographic images such as Panoramic x-ray image and Cephalometric x-ray image. So dental practitioners can get the accurate anatomical knowledge of the patient on each view and it helps them to do precise diagnosis.

(5) 3D image construction

The Accurex™ has the capability of constructing 3D model from original axial images. The method of 3D image construction is Volume rendering. And multiple volume rendering is supported. The volume rendering image can be manipulated by CT value, Color, Opacity, Window Level and width value and also can be edited by CT value threshold and 3D cutting tool. And Virtual Endoscopy is supported. Also the Accurex™ supports high-quality zoom function for studying some subtle and fine structures with better quality of volume rendering model. 3D Algorithm was cleared in Vworks((K013878).

(6) Image projection

The Accurex™ can generate some projection images such MIP(Maximum Intensity Projection), MinIP(Minimum Intensity Projection), Ray-sum image.

(7) Nerve Creation and Display

The Accurex™ has nerve creation function. Users can draw a nerve line on cross-sectional and panoramic images as well as axial images, And then users can see the intersection shape of nerve on each view.

(8) Report

The Accurex™ provides a report template. The report template makes it possible to help some results or opinion for diagnosis. Users can capture some necessary images on all screens with Pane-Capture or Region-Capture options and insert the captured images to their report. So users can make their unique report more quickly and easily as intuitive user-familiar interface. Also the report can be exported to HTML or XML format document.

(9) Measurement

The Accurex™ provides users needful measurement functions. Users can use 2D

measurement tools such as distance, angle, and area, CT value profile and 3D measurement tools such as distance, angle.

(10) Capture and Print

The Accurex™ has a capability of image capture. The captured images can be print by Window printer and DICOM printer.

3) Information of the image format

The Accurex™ can load only DCM files and save results as DCM, BMP and JPG files.

- **DCM** : DICOM (Digital Image Communication in Medicine) is a Standard Protocol to exchange and transfer the data acquired by Medical Image devices such as a CT, MR, 3D US, etc. It is designated as a Standard Protocol by ACR-NEMA (American College of Radiology-National Electrical Manufacturers Association) and now adopted by most Medical Imaging Devices. The Accurex™ 2.0 is adaptable technically for all data of DICOM 3.0.
  Reference : Digital Imaging and Communications in Medicine (DICOM) ACR-NEMA Standards Publication PS 3.1~PS 3.16 2003.
- **BMP** : The standard bit-mapped graphics format used in the Windows environment. By convention, graphics files in the BMP format end with a BMP extension. BMP files store graphics in a format called device-independent bitmap (DIB).
- **JPG/JPEG** : Short for "Joint Photographic Experts Group", the original name of the committee that wrote the standard. JPG is one of the image file formats supported on the Web. JPG is a lossy compression technique that is designed to compress color and grayscale continuous-tone images, but the Accurex™ does not compress original graphics any more, that is to say lossless compression.
  JPG images support 16 million colors and are best suited for photographs and complex graphics.

6. Indication for use :

Use as a software for the display and 3D visualization of dental image files from scanning devices such as CT, MRI for radiologists, dental clinicians and practitioners to acquire, process, render, review, store, print and distribute DICOM 3.0 complaint image studies, utilizing standard PC hardware.

7. Comparison with predicate device :

CyberMed, Inc., believes that the Accurex 3D dental image processing software is substantially equivalent to Vworks of CyberMed, Inc..

8. Conclusions :

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification CyberMed, Inc. concludes that Accurex is safe and effective and substantially equivalent to predicate devices as described herein.

9. CyberMed, Inc. will update and include in this summary any other information deemed seasonably necessary by the FDA.

END

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

MAY - 9 2006

CyberMed, Inc.
% Mr. Marc M. Mouser
Senior Project Engineer/Program Reviewer
Underwriters Laboratories, Inc.
2600 NW Lake Road
CAMAS WASHINGTON 98607

Re: K061126
Trade/Device Name: Accurex
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: April 5, 2006
Received: April 24, 2006

Dear Mr. Mouser:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number(if known): K061126

Device Name: Accurex

Indications for Use:

Use as a software for the display and 3D visualization of dental image files from scanning devices such as CT, MRI for radiologists, dental clinicians and practitioners to acquire, process, render, review, store, print and distribute DICOM 3.0 complaint image studies, utilizing standard PC hardware.

Prescription Use ✓ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation(ODE)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K061126